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09/918,365	07/30/2001	Eugene T. Michal	ACS 55933	1073

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EXAMINER	
MICHENER, JENNIFER KOLB	

ART UNIT	PAPER NUMBER
1762	

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/918,365	Applicant(s) MICHAL ET AL.	
	Examiner Jennifer Kolb Michener	Art Unit 1762	

-- The MAILING DATE of this communication appears on the cover she t with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 October 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-46* is/are pending in the application.

4a) Of the above claim(s) *19-33 and 35-46* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-18 and 34* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *30 July 2001* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 5.
4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Examiner appreciates Applicant's election of method claims 1-46 and cancellation of non-elected claims 47-79 in the previous office action and response. The following restriction between the method Inventions is supplemental to that which was made in 9/2003:

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

   I. Claims 1-18 and 34-38, drawn to a method of direct immobilization coating of a material to a base coat, classified in class 427, subclass 2.24.

   II. Claims 19-33, drawn to a method of coating a material via polyethylene glycol to a base coat, classified in class 427, subclass 299.

   III. Claims 39-46, drawn to a method of immobilization of a material to a base coat using a carbodiimide reaction, classified in class 427, subclass 409.

The inventions are distinct, each from the other because of the following reasons:

2. Inventions I, II and III are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different modes of operation, functions, and effects are not disclosed as capable of use together. A method of direct coating, a

method of coating via polyethylene glycol spacers, and a method of coating using carbodiimide reactions are all unrelated.

3. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

4. Because these inventions are distinct for the reasons given above and the search required for each of the Groups is not required for the others, restriction for examination purposes as indicated is proper.

5. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

6. This application contains claims directed to the following patentably distinct species of the claimed invention: unfractionated heparin, desulfated heparin, benzalkonium heparin, and TDMA-heparin.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1 and 34 are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim

is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

7. During a telephone conversation with John Nagy in December 2003 a provisional election was made without traverse to prosecute the invention of Group I, claims 1-18 and 34-38 and the species of unfractionated heparin in claim 13. Affirmation of this election must be made by applicant in replying to this Office action. Non-elected claims 19-33 and 39-49 and non-elected species of claims 35-38 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Therefore, elected group and species claims 1-18 and 34 are examined, below.

Specification

8. The title of the invention, "Covalently immobilized heparin into and onto functionalized polyurethane" is not descriptive of the invention now claimed. A new title is required that is clearly indicative of the invention to which the claims are directed. Specifically, the application is currently drawn to a method, not to a composition such as "immobilized heparin". Furthermore, the claims are not limited to covalent attachment or to polyurethane substrates, as the title would indicate.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 1-18 and 34 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The phrase "immobilizing the anti-thrombogenic material directly to chemically functional groups within the base coat layer on...the medical device" is confusing. The specification on page 5 defines "immobilize" as to attach the antithrombogenic agent to a support member through at least one intermediate component. It is not clear how the anti-thrombogenic material can be *directly* attached if it is attached via an intermediate component.

Double Patenting

3. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

4. Claims 1-18 and 34 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-9 and 14 of U.S. Patent No. 6,221,425 and claims 1-17 of U.S. Patent No. 6,656,517. Although the conflicting claims are not identical, they are not patentably distinct from each other. While grouped together in different ways, the limitations of the instant application are present throughout the claims of the patents.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in-

> (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effect under this subsection of a national application published under section 122(b) only if the international application designating the United States was published under Article 21(2)(a) of such treaty in the English language; or
> (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that a patent shall not be deemed filed in the United States for the purposes of this subsection based on the filing of an international application filed under the treaty defined in section 351(a).

6. Claims 1-3, 5, 7, 11-12, 15-17 are rejected under 35 U.S.C. 102(b) as being anticipated by Cahalan et al. (US Pat. 5,607,475).

Cahalan teaches a method of coating an implantable medical device (col. 1, line 15) with a grafting component (col. 5, lines 20-30). The grafting component is an acrylate compound (col. 4, line 26). The grafted surface is treated with a covalent binding agent such as a carbodiimide-containing compound (col. 7, line 3-7 and 16). The grafting component is polymerized to graft it to the device (col. 3, lines 50-57). The binding compound binds to the grafting component, thus forming a "base coat" on the device. To this layer is applied a biomolecule top coating which is covalently attached to the grafted surface via functional groups present on the biomolecule (col. 4, lines 11-14).

Cahalan coats stents with his method (col. 4, line 36), which is inclusive of the outside.

Regarding claims 11-12, the topcoat of Cahalan is a biomolecule, such as a heparin therapeutic agent. This topcoat is covalently bonded to the grafted surface via pendant functional groups, such as carboxyl or amine (col. 4, lines 10-14). The examples teach the use of a solution to apply such a topcoat.

Regarding claim 7, the medical article of Applicant is metal and contains a vinyl silane coating prior to graft polymerization of the grafting agent.

Regarding the limitations of claims 15-17, not previously addressed in regard to the other independent claim, Cahalan teaches the application of a spacer molecule (col. 6, line 29). These spacer molecules contain functional groups at opposite ends of the molecule for coupling to the previous and subsequent chemicals. The spacer is an amine, containing the functional group required by Applicant in his specification to meet the definition of "end-immobilization".

7. Claims 1-12, 15-17, 34 are rejected under 35 U.S.C. 102(e) as being anticipated by Michal et al. (U.S. 6,287,285 B1).

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

Regarding claims 1-3, 11, 16-17, and 34, Michal et al. teach a method of immobilizing heparin, an anti-thrombogenic agent, to an implantable medical device, such as a stent. A base coat is applied to and polymerized on the device to which the heparin is attached via functional groups. Regarding claim 4, the base coat of Michal comprises a

grafting material, binding material, photoinitiator, and a solvent. The binding component of Michal may be an amine or aldehyde group, such as cinnamaldehyde, as required in claims 5-6, and the grafting component may be polyurethane acrylate, as required in claims 7-8. The stent coating is polymerized by irradiating with UV light for 8 minutes, as required by claim 9. The solvent of Michal may be ketone compounds or water, as required by claims 10 and 12. Regarding claims 15, the binding component of Michal may be an amine which is the functional group required by Applicant in his specification to meet the definition of "end immobilization". (See abstract; col. 2, lines 15-30, 55-57; col. 4, line 7; col. 6, lines 55-65; col. 7, lines 30-35, 59, and 67; col. 8; col. 10, line 55- col. 11, line 15; col. 13, lines 22-28; Example 4.)

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

9. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

10. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

11. Claims 14 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cahalan et al.

Cahalan et al. teach that which is disclosed above. What Cahalan fails to teach the is time, temperature, and neutral pH of the reaction between the heparin and the base coat. It is Examiner's position, however, that it would have been obvious to one of ordinary skill in the art to select an appropriate time, temperature, and pH for coating a substrate with heparin as such variables are cause effective. Time and temperature determine the rate and degree of reaction. An implant for the human body would also be safest when neutral, or pH 7, as claimed.

It is well settled that determination of optimum values of cause effective variables such as these process parameters is within the skill of one practicing in the art. *In re Boesch*, 205 USPQ 215 (CCPA 1980).

12. Claims 14 and 18 are rejected under 35 U.S.C. 103(a) as being obvious over Michal et al.

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art only under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 103(a) might be overcome by: (1) a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not an invention "by another"; (2) a showing of a date of invention for the claimed subject matter of the application which corresponds to subject matter disclosed but not claimed in the reference, prior to the effective U.S. filing date of the reference under 37 CFR 1.131; or (3) an oath or declaration under 37 CFR 1.130 stating that the application and reference are currently owned by the same party and that the inventor named in the application is the prior inventor under 35 U.S.C. 104, together with a terminal disclaimer in accordance with 37 CFR 1.321(c). For applications filed on or after November 29, 1999, this rejection might also be overcome by showing that the subject matter of the reference and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person. See MPEP § 706.02(l)(1) and § 706.02(l)(2).

Michal teaches that which is disclosed above, but fails to teach the time, temperature and neutral pH of these dependent claims. It is Examiner's position that selection of these cause-effective variables would have been obvious for those reasons outlined above.

13. Claim 13 is rejected under 35 U.S.C. 103(a) as being unpatentable over either Cahalan or Michal in view of Hughes et al.

Cahalan and Michal teach coating stents with heparin in the manners described above, but fail to teach a specific type of heparin to be chosen from the broad class of "heparin".

Examiner notes that unfractionated heparin is a member species of the genus "heparin" and therefore it would have been obvious to select unfractionated heparin from the broad class of heparin. Additionally, Examiner cites Hughes to teach the same.

Hughes teaches coating a stent with polymer and then with heparin, specifically unfractionated heparin (P0155).

Since Cahalan and Michal teach coating stents with a polymer base coat and then heparin and Hughes teaches coating stents with a polymer base coat and then, specifically, unfractionated heparin, Hughes would have reasonably suggested the use of unfractionated heparin in the method of Cahalan or Michal. It would have been obvious to one of ordinary skill in the art to use the teachings of Hughes in the method of Cahalan or Michal with the expectation of successful results since Hughes teaches the suitability of this type of heparin on polymer-coated stents.

Conclusion

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer Kolb Michener whose *new* telephone number is

571-272-1424. The examiner can normally be reached on Monday through Thursday and alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shrive P. Beck can be reached on 571-272-1415. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9310 for regular communications and 703-872-9311 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0661.

Jennifer Kolb Michener
Patent Examiner
Technology Center 1700
December 12, 2003